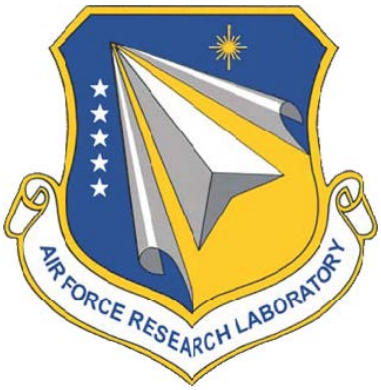

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Comparison of iSTAT and EPOC Blood Analyzers

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14. ABSTRACT
Point-of-care (POC) testing is an essential component of far forward and en route care. Prolonged field care requires accurate blood analysis across a range of environmental conditions and, in extreme circumstances, use beyond the expiration date. We compared gold standard laboratory testing to two POC devices—iSTAT and EPOC—with and without expired cartridges and conditioned cartridges. The study was approved by the Institutional Review Boards of the University of Cincinnati Medical Center and the Air Force Research Laboratory. Informed consent was obtained from subjects or their surrogate. At the time of standard-of-care (SOC) blood draws, additional blood was simultaneously analyzed using the POC devices. The EPOC and iSTAT devices were tested with current and expired cartridges (>30 days past expiration date) as well as conditioned cartridges (24 hours at extremes of temperature for 2 hours, -20°F or 130°F). Results are expressed as the number of measurements that are ±10% of SOC, >10% of SOC, and the number of failed measurements for selected variables. Mean differences were calculated and Bland Altman plots were used to determine bias and precision. Both POC devices performed as stated at normal conditions. Expired and conditioned cartridges altered accuracy for a number of variables. Exposure to extreme heat (130°F) resulted in a loss of accuracy and an increase in the number of failed measurements. Use of expired cartridges exposed to high temperatures for either device can result in spurious results, particularly for blood gases.

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1.0 SUMMARY

Point-of-care (POC) testing is an essential component of far forward and en route care. Prolonged field care requires accurate blood analysis across a range of environmental conditions and, in extreme circumstances, use beyond the expiration date. We compared gold standard laboratory testing to two POC devices—iSTAT and EPOC—with and without expired cartridges and conditioned cartridges. The study was approved by the Institutional Review Boards of the University of Cincinnati Medical Center and the Air Force Research Laboratory. Informed consent was obtained from subjects or their surrogate. At the time of standard-of-care (SOC) blood draws, additional blood was simultaneously analyzed using the POC devices. The EPOC and iSTAT devices were tested with current and expired cartridges (>30 days past expiration date) as well as conditioned cartridges (24 hours at extremes of temperature for 2 hours, -20°F or 130°F). Results are expressed as the number of measurements that are ±10% of SOC, >10% of SOC, and the number of failed measurements for selected variables. Mean differences were calculated and Bland Altman plots were used to determine bias and precision. Both POC devices performed as stated at normal conditions. Expired and conditioned cartridges altered accuracy for a number of variables. Exposure to extreme heat (130°F) resulted in a loss of accuracy and an increase in the number of failed measurements. Use of expired cartridges exposed to high temperatures for either device can result in spurious results, particularly for blood gases.

2.0 BACKGROUND

Blood analysis is a critical aspect of evaluating and caring for the ill/injured warrior. In particular, point-of-care (POC) testing affords extended capabilities beyond the confines of a fixed medical facility. Military units currently incorporate the iSTAT blood analyzer (Abbott Laboratories, Abbott Park, IL) in their deployable set kits as the technology of choice for blood analysis. The Air Force Special Operations Command is considering an alternate device as a potential replacement for the iSTAT. Statistical data suggest there is a need for a more accurate and timely measurement device to provide this analysis throughout the continuum of care [1-6]. The EPOC blood analyzer (Epocal Inc., Ottawa, Ontario, Canada) is being considered as an updated solution for blood analysis requirements. Published data demonstrate the EPOC has increased accuracy and 75% reduction in time for provision of results [7-9]. This study involves the estimation of the biases and limits of agreement between the iSTAT and EPOC blood analyzers.

During military operations, the use of blood measurements remains important to patient care. In remote environments, devices and the components are exposed to extremes of temperature, and during prolonged field care, consumables (cartridges) may pass the expiration date. In the absence of resupply, these expired consumables may be used for diagnostic testing. The accuracy of devices using expired consumables has not been studied. We included a group of cartridges that were past the expiration date and a group that had been exposed to temperature extremes.

3.0 METHODS

The study was approved by the Institutional Review Boards of the University of Cincinnati Medical Center and the Air Force Research Laboratory. Patients admitted to the surgical intensive care unit following traumatic injury or surgical illness meeting the inclusion criteria (age 18-55) were eligible for the study. Informed consent was obtained from subjects or their surrogate. When a standard-of-care (SOC) blood sample was drawn (for arterial blood gas, hemoglobin (Hgb) and hematocrit (Hct), or serum electrolytes), an additional sample of 1 mL was drawn from the patient, up to five times. No more than 5 mL (1 teaspoon) was drawn from the patient. The samples were instantly analyzed on both the iSTAT and EPOC analyzers using the appropriate cartridge for the SOC-ordered tests.

The study compared the accuracy of the iSTAT and EPOC analyzers' measurements of pH, partial pressure of carbon dioxide (CO_2), partial pressure of oxygen, sodium (Na+), potassium (K+), calcium, glucose (Glu), Hct, lactate (Lac), creatinine (Cr), and chloride (calculated total CO_2, bicarbonate (HCO_3), base excess (BE) extra cellular fluid, BE blood, sulfur dioxide, Hgb) to gold standard measurements conducted by the central laboratory.

The study also compared the accuracy of iSTAT and EPOC analyzers' measurements using expired (>30 days past expiration date) and expired-conditioned cartridges (>30 days past expiration date, 24 hours at extremes of temperature for 2 hours, -20°F or 130°F).

The test results from the iSTAT and EPOC analyzers were not used in patient treatment or clinical management decisions; any clinically significant test results were reported to the treatment team. The iSTAT and EPOC analyzers both have U.S. Food and Drug Administration 510k clearance.

4.0 RESULTS

Data from 124 subjects were included. Representative data are for iSTAT, iSTATexpired, iSTATconditioned (hot or cold) and EPOC, EPOC expired, EPOCconditioned (hot or cold) (Table 1).

The main finding is the pH for the EPOC expired cartridges and those exposed to extremes of temperature yielded a statistically and clinically important difference. The pH is the negative log of the hydrogen ion concentration, meaning a change of 0.1 represents a significant increase in the hydrogen ion concentration. The difference between 7.37 and 7.26 changes the clinical interpretation from normal acid base status to acidosis, perhaps triggering institution of ventilatory support or delivery of agents to increase pH. Even though the mean difference (bias) data for arterial partial pressure of oxygen (PaO_2), arterial partial pressure of CO_2 ($PaCO_2$), Glu, and HCO_3 are statistically significant, the majority of differences are clinically insignificant and would not promote the caregiver to change course of treatment. On the other hand, the statistically significant mean difference (bias) for pH, BE, blood urea nitrogen (BUN), and Lac could influence caregivers to change medical treatment when it is not necessary.

Data shown in Table 2 are the percentage of measurements within 10% of the laboratory (SOC) value, measurements where the POC value is >10% of the SOC value, and the percentage of failed measurements for select variables. A failed measurement occurs when the blood is inserted into the cartridge but no value is obtained.

Table 1. Blood Analyzer Results

Label	Device	Mean	SD	Bias = Mean Difference	SD of Mean Difference	Lower Limit	Upper Limit
pH	Control	7.38	0.068				
pH	EPOC	7.37	0.068	-0.009	0.021	-0.050	0.032
pH	EPOC_COLD	7.26	0.089	-0.120	0.070	-0.258	0.018
pH	EPOC_EXP	7.27	0.058	-0.092	0.041	-0.172	-0.012
pH	EPOC_HOT	7.28	0.079	-0.117	0.071	-0.257	0.023
pH	ISTAT_CG4	7.36	0.068	-0.024	0.019	-0.061	0.012
pH	ISTAT_CG4_COLD	7.35	0.076	-0.030	0.016	-0.063	0.003
pH	ISTAT_CG4_EXP	7.35	0.068	-0.031	0.019	-0.068	0.006
pH	ISTAT_CG4_HOT	7.37	0.070	-0.031	0.022	-0.074	0.0121
$PaCO_2$	Control	44.8	6.763				
$PaCO_2$	EPOC	47.6	7.598	2.792	2.795	-2.686	8.269
$PaCO_2$	EPOC_COLD	48.0	6.875	3.482	2.248	-0.924	7.888
$PaCO_2$	EPOC_EXP	48.9	7.371	4.096	3.084	-1.950	10.142
$PaCO_2$	EPOC_HOT	47.8	7.365	5.511	3.127	-0.619	11.641
$PaCO_2$	ISTAT_CH4	46.4	7.617	1.616	2.642	-3.562	6.795
$PaCO_2$	ISTAT_CH4_COLD	47.5	6.469	2.927	1.924	-0.844	6.699
$PaCO_2$	ISTAT_CH4_EXP	47.2	7.549	3.278	3.212	-3.017	9.572
$PaCO_2$	ISTAT_CH4_HOT	46.1	7.177	3.789	3.324	-2.726	10.304
PaO_2	Control	93.5	25.705				
PaO_2	EPOC	93.7	26.499	0.18	24.766	-48.36	48.72
PaO_2	EPOC_COLD	109.2	30.969	11.355	18.109	-24.139	46.849
PaO_2	EPOC_EXP	95.1	30.069	1.592	25.673	-48.726	51.91
PaO_2	EPOC_HOT	100.1	39.406	5.1667	45.109	-83.247	93.58
PaO_2	ISTAT_CG4	95.9	29.936	2.44	25.237	-47.025	51.905
PaO_2	ISTAT_CG4_COLD	112.6	28.925	14.818	18.389	-21.225	50.861
PaO_2	ISTAT_CG4_EXP	102.3	35.489	4.889	30.782	-55.443	65.221
PaO_2	ISTAT_CG4_HOT	94.6	32.408	-0.333	37.253	-73.348	72.682
HCO_3	Control	26.6	4.214				
HCO_3	EPOC	27.9	4.16	1.332	0.814	-0.265	2.929
HCO_3	EPOC_COLD	20.5	4.056	-4.333	3.808	-11.796	3.129
HCO_3	EPOC_EXP	23.4	4.205	-2.394	1.816	-5.953	1.164
HCO_3	EPOC_HOT	22.2	4.304	-3.2	2.776	-8.641	2.241
HCO_3	ISTAT_CG4	26.3	4.009	-0.3	0.942	-2.146	1.546
HCO_3	ISTAT_CG4_COLD	26.4	4.479	0.264	0.79	-1.285	1.813
HCO_3	ISTAT_CG4_EXP	26.2	4.668	0.272	1.049	-1.785	2.329
HCO_3	ISTAT_CG4_HOT	27.1	5.376	0.589	1.042	-1.454	2.631
BE	Control	1.37	4.503				
BE	EPOC	2.69	4.839	1.328	0.841	-0.32	2.976
BE	EPOC_COLD	-6.53	5.403	-6.35	4.731	-15.624	2.924
BE	EPOC_EXP	-3.44	4.801	-3.844	2.329	-8.409	0.721
BE	EPOC_HOT	-4.47	5.328	-4.8143	3.627	-11.924	2.295
BE	ISTAT_CG4	0.88	4.649	-0.488	0.93	-2.3112	1.335
BE	ISTAT_CG4_COLD	0.82	5.528	-0.091	1.061	-2.169	1.988
BE	ISTAT_CG4_EXP	0.56	5.36	-0.183	1.053	-2.248	1.881
BE	ISTAT_CG4_HOT	2.11	6.274	0.578	1.089	-1.558	2.713

Table 1. Blood Analyzer Results (continued)

Label	Device	Mean	SD	Bias = Mean Difference	SD of Mean Difference	Lower Limit	Upper Limit
SaO_2	Control	94.6	3.751				
SaO_2	EPOC	94.5	6.509	-0.132	5.899	-11.695	11.432
SaO_2	EPOC_COLD	96.8	3.196	0.3	1.9	-3.425	4.025
SaO_2	EPOC_EXP	91.9	10.157	-2.805	9.662	-21.742	16.132
SaO_2	EPOC_HOT	89.9	14.852	-4.429	15.796	-35.388	26.531
SaO_2	ISTAT_CG4	94.3	6.804	-0.352	6.105	-12.317	11.613
SaO_2	ISTAT_CG4_COLD	96.7	3.875	1.673	1.466	-1.1999	4.545
SaO_2	ISTAT_CG4_EXP	95.1	6.749	-0.047	6.536	-12.857	12.763
SaO_2	ISTAT_CG4_HOT	93.8	8.497	-0.656	9.253	-18.791	17.481
Lac	Control	2.4	2.004				
Lac	EPOC	2.61	2.124	0.21	0.203	-0.189	0.609
Lac	EPOC_COLD	1.95	1.528	0.188	0.257	-0.316	0.692
Lac	EPOC_EXP	2.7	2.503	0.282	0.531	-0.759	1.324
Lac	EPOC_HOT	4.75	3.8178	0.753	1.003	-1.214	2.719
Lac	ISTAT_CG4	2.43	2.004	0.029	0.134	-0.232	0.291
Lac	ISTAT_CG4_COLD	1.26	0.824	0.185	0.262	-0.329	0.699
Lac	ISTAT_CG4_EXP	2.64	2.345	0.079	0.165	-0.244	0.402
Lac	ISTAT_CG4_HOT	3.61	3.008	0.252	0.168	-0.077	0.581
Na	Control	138.23	6.150				
Na	EPOC	139.87	7.433	1.635	2.124	-2.528	5.797
Na	EPOC_COLD	138.44	8.702	-0.375	2.604	-5.480	4.730
Na	EPOC_EXP	137.29	6.969	-0.942	2.173	-5.201	3.317
Na	EPOC_HOT	137.47	6.820	-0.647	2.691	-5.922	4.628
Na	ISTAT_CHEM8	138.02	7.650	-0.212	4.207	-8.457	8.034
Na	ISTAT_CHEM8_COLD	139.24	7.207	0.765	1.602	-2.375	3.904
Na	ISTAT_CHEM8_EXP	139.11	6.944	0.278	1.799	-3.247	3.803
Na	ISTAT_CHEM8_HOT	138.17	6.157	-0.222	2.045	-4.231	3.786
K	Control	4.25	0.594				
K	EPOC	4.17	0.547	-0.085	0.323	-0.717	0.548
K	EPOC_COLD	4.28	0.543	-0.075	0.224	-0.513	0.363
K	EPOC_EXP	4.08	0.533	-0.165	0.309	-0.772	0.441
K	EPOC_HOT	4.01	0.493	-0.153	0.265	-0.672	0.366
K	ISTAT_CHEM8	4.10	0.506	-0.148	0.343	-0.819	0.523
K	ISTAT_CHEM8_COLD	4.32	0.593	-0.088	0.141	-0.364	0.188
K	ISTAT_CHEM8_EXP	4.13	0.581	-0.122	0.214	-0.542	0.297
K	ISTAT_CHEM8_HOT	4.02	0.491	-0.156	0.273	-0.69	0.379
Hgb	Control	9.08	1.753				
Hgb	EPOC	9.5	2.81	0.488	2.493	-4.399	5.374
Hgb	EPOC_COLD	8.89	2.909	-0.459	1.65	-3.693	2.774
Hgb	EPOC_EXP	9.14	2.58	0.063	2.112	-4.076	4.202
Hgb	EPOC_HOT	8.38	1.991	-0.608	1.36	-3.274	2.059
Hgb	ISTAT_CHEM8	9.43	2.303	0.331	1.831	-3.257	3.918
Hgb	ISTAT_CHEM8_COLD	8.84	2.657	-0.514	1.434	-3.324	2.296
Hgb	ISTAT_CHEM8_EXP	9.07	2.363	-0.06	1.648	-3.29	3.17
Hgb	ISTAT_CHEM8_HOT	8.69	1.933	-0.256	1.844	-3.869	3.358

Table 1. Blood Analyzer Results (concluded)

Label	Device	Mean	SD	Bias = Mean Difference	SD of Mean Difference	Lower Limit	Upper Limit
Hct	Control	27.39	5.113				
Hct	EPOC	28.15	8.268	0.764	7.202	-13.351	14.879
Hct	EPOC_COLD	26.14	8.587	-2.282	4.835	-11.759	7.195
Hct	EPOC_EXP	26.82	7.569	-0.564	5.998	-12.32	11.191
Hct	EPOC_HOT	24.04	6.327	-2.874	4.311	-11.323	5.575
Hct	ISTAT_CHEM8	27.48	7.029	0.093	5.413	-10.517	10.703
Hct	ISTAT_CHEM8_COLD	26	7.819	-2.418	3.997	-10.252	5.415
Hct	ISTAT_CHEM8_EXP	26.68	6.932	-0.914	4.711	-10.147	8.319
Hct	ISTAT_CHEM8_HOT	25.56	5.659	-1.356	5.431	-11.999	9.288
BUN	Control	23.78	21.466				
BUN	ISTAT_CHEM8	21.96	20.122	-1.824	3.071	-7.842	4.195
BUN	ISTAT_CHEM8_COLD	27	22.119	-0.706	1.759	-4.154	2.743
BUN	ISTAT_CHEM8_EXP	24.97	22.827	-1.857	2.702	-7.154	3.439
BUN	ISTAT_CHEM8_HOT	25.71	27.737	0.176	1.741	-3.235	3.588
Cr	Control	1.611	1.642				
Cr	EPOC	1.695	1.77	0.139	0.268	-0.385	0.665
Cr	EPOC_COLD	1.794	1.428	-0.013	0.33	-0.659	0.634
Cr	EPOC_EXP	1.683	1.762	-0.069	0.327	-0.709	0.572
Cr	EPOC_HOT	1.383	1.321	-0.014	0.182	-0.371	0.343
Cr	ISTAT_CHEM8	1.646	1.665	0.035	0.091	-0.144	0.214
Cr	ISTAT_CHEM8_COLD	2.194	2.323	-0.026	0.159	-0.337	0.284
Cr	ISTAT_CHEM8_EXP	1.808	1.899	0.021	0.108	-0.191	0.232
Cr	ISTAT_CHEM8_HOT	1.378	1.12	-0.022	0.127	-0.271	0.227
Glu	Control	134.38	48.827				
Glu	EPOC	131.8	52.448	-2.582	9.506	-21.213	16.049
Glu	EPOC_COLD	120.13	45.469	-6.375	7.822	-21.706	8.956
Glu	EPOC_EXP	126.76	46.251	-7.618	9.036	-25.329	10.092
Glu	EPOC_HOT	132.17	46.276	-10.28	10.813	-31.471	10.915
Glu	ISTAT_CHEM8	134.51	50.251	0.127	5.959	-11.554	11.809
Glu	ISTAT_CHEM8_COLD	140.41	69.719	2.059	5.595	-8.908	13.02
Glu	ISTAT_CHEM8_EXP	141.03	58.562	1.568	5.867	-9.931	13.066
Glu	ISTAT_CHEM8_HOT	143.79	52.028	0.211	7.502	-14.494	14.915

SaO_2 = oxygen saturation; SD = standard deviation.
Yellow highlighted cells represent statistically significant data.

Table 2. Percentage of Measurements within 10% of the Laboratory (SOC) Value, Measurements Where the POC Value is >10% of the SOC Value, and the Percentage of Failed Measurements for Select Variables

Device	iSTAT	iSTATexp	iSTATcold	iSTAThot	EPOC	EPOCexp	EPOCcold	EPOChot
pH	100/0/0	93/7/0	100/0/0	100/0/0	100/0/0	77/23/0	55/0/45	90/0/10
$PaCO_2$	94/6/0	87/7/6	83/17/0	95/5/0	94/6/0	63/37/0	73/27/0	58/42/0
PaO_2	61/39/0	58/35/7	50/50/0	53/47/0	77/23/0	67/33/0	45/55/0	53/47/0
HCO_3	97/3/0	90/3/7	100/0/0	89/11/0	94/6/0	50/27/23	18/46/36	68/21/11
BE	27/73/0	32/68/0	9/91/0	6/94/0	20/80/0	0/100/0	0/100/0	6/94/0
SaO_2	100/0/0	90/10/0	100/0/0	100/0/0	100/0/0	77/23/0	55/45/0	89/11/0
Lac (mmol)	64/36/0	73/27/0	40/40/20	60/40/0	67/33/0	53/40/7	40/60/0	25/75/0
Na (mmol/L)	98/2/0	100/0/0	100/0/0	100/0/0	100/0/0	100/0/0	94/6/0	96/4/0
K (mmol/L)	96/4/0	96/2/2	100/0/0	97/3/0	96/4/0	94/6/0	88/6/6	92/4/4
Hgb (g/dL)	58/41/1	51/49/0	68/32/0	44/56/0	69/31/0	50/50/0	73/27/0	44/54/1
Hct	54/46/0	49/51/0	59/41/0	41/59/0	70/30/0	53/47/0	73/27/0	50/50/0
BUN	56/44/0	57/43/0	82/18/0	71/29/0	NA	NA	NA	NA
Cr (mg/dL)	71/29/0	79/21/0	82/18/0	77/23/0	52/41/7	26/52/22	12/53/35	37/41/22
Glu (mg/dL)	96/4/0	96/4/0	100/0/0	94/6/0	82/18/0	77/23/0	71/23/6	66/31/3

5.0 DISCUSSION

Both POC devices performed as stated at normal conditions, although some variables (PaO_2, BE, Lac, Hgb, Hct, and BUN) were not as accurate as electrolytes (sodium, potassium, etc.). Expired and conditioned cartridges altered accuracy for a number of variables. Exposure to extreme heat (130°F) resulted in a loss of accuracy and an increase in the number of failed measurements with both devices. Use of expired cartridges exposed to high temperatures for either device can result in spurious results, particularly for blood gases (pH, $PaCO_2$, PaO_2). Failure of creatinine measurements with the EPOC device was increased threefold with expired and conditioned cartridges.

Even though the mean difference (bias) data for PaO_2, $PaCO_2$, Glu, and HCO_3 are statistically significant, the majority of changes are clinically insignificant and would not promote the caregiver to change course of treatment. However, the statistically significant mean difference (bias) for pH, BE, BUN, and Lac will influence caregivers to change medical treatment when it is not necessary.

Limitations of this study include relatively small sample size for any given measurement and the controlled environment (hospital vs. field). Cartridges were exposed to temperatures in an environmental chamber under controlled conditions, which may not represent the deployed conditions.

The EPOC device, which does not require refrigeration (a logistical advantage), was impacted more significantly by the exposure to temperature extremes. These findings are important for logistics and clinical care. Using data from expired cartridges or those exposed to high temperature should be avoided. In select circumstances, expired cartridges can provide accurate measurements, but clinicians should be aware of those possible limitations and failures.

6.0 CONCLUSIONS

Use of expired cartridges is not recommended but appears to be a viable option in situations where supplies are limited. Cartridges that do not require refrigeration may represent a logistical advantage. While a number of values were statistically significant, these small differences were not clinically important except for pH and BE.

7.0 REFERENCES

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LIST OF SYMBOLS, ABBREVIATIONS, AND ACRONYMS

BE	base excess
BUN	blood urea nitrogen
CO_2	carbon dioxide
Cr	creatinine
Glu	glucose
HCO_3	bicarbonate
Hct	hematocrit
Hgb	hemoglobin
K	potassium
Lac	lactate
Na	sodium
$PaCO_2$	arterial partial pressure of carbon dioxide
PaO_2	arterial partial pressure of oxygen
POC	point of care
SaO_2	oxygen saturation
SD	standard deviation
SOC	standard of care